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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,303	Applicant(s) MEUTERMANS ET AL.
	Examiner SCARLETT GOON	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,
 WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 2,7,9-13,15,16,19-21 and 23 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-6,8,14,17,18,22 and 24 is/are rejected.
 7) Claim(s) 1, 4 and 5 is/are objected to.
 8) Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No.(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No.(s)/Mail Date: _____
 5) Notice of Informal Patent Application
 6) Other: _____

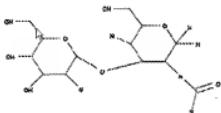
DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 21 January 2009 in claims 14, 17 and 18 are amended to further clarify the claimed invention.

Claims 1-24 are pending in the instant application.

Claims 2, 7, 9-13, 15, 16, 19-21 and 23 were previously withdrawn from further consideration in the Office Action dated 20 October 2008 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or nonelected species, there being no allowable generic or linking claim.

The subgenus structure shown below has been found to be free of the prior art, as indicated in the Office Action dated 20 October 2008, and the search was extended to include a method comprising compounds wherein T is O.



Claims 1, 3-6, 8, 14, 17, 18, 22 and 24 are examined on its merits herein.

Priority

This application is a National Stage entry of PCT/AU03/01377 filed on 16 October 2003 and claims priority to Australia foreign application 2002952121 filed on 17 October 2002. A certified copy of the foreign priority document in English has been received.

Rejections Withdrawn

Applicant's amendment, filed 21 January 2009, with respect to the rejections of claims 14, 17 and 18 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, has been fully considered and is persuasive because the claim as amended recite the substituents of A within the claim rather than referring to a Table in the Specification.

Applicant's arguments filed 21 January 2009 with respect to the rejection of claim 1 as being unpatentable over Oki *et al.*, in view of Sawada *et al.* and Nishio *et al.*, have been fully considered and are persuasive because the references have not sufficiently shown that the absence of antifungal activity in the aglycone portion of pradimicin A can be translated to absence of antibacterial activity in the aglycone portion of the same molecule.

These rejections have been withdrawn.

Claim Objections

Claims 1, 4 and 5 are objected to because of the following informalities:
The conjunction "and" should be inserted before the last member of each selectable group of Claim 1 to put the claim in proper Markush format.

The claims are objected to because they include reference characters which are not enclosed within parentheses.

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

Appropriate correction is required.

The following are new ground(s) of rejections.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 8, 14, 17, 18, 22 and 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The absence of a transitional phrase in claim 1 renders the claims herein indefinite. Transitional phrases are used to define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. See MPEP § 2111.03 [R-3]. Thus, in the absence of such transitional phrase, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant is suggested to insert a transitional phrase such as "comprising" or other transitional phrase into claim 1.

The recitation "R is selected from the group consisting of: H, alkyl, alkenyl, alkynyl, heteroalkyl, aryl, heteroaryl, arylalkyl or heteroarylalkyl of 1 to 20 carbon atoms" in claim 1 renders the claims herein indefinite. It is unclear whether the limitation of "1 to 20 carbon atoms" refers only to heteroarylalkyl compounds, the total number of carbons in the entire heteroarylalkyl group, only the alkyl portion of the heteroarylalkyl group, whether it refers to all members of the R group, or only specific members of the R group. If the limitation refers to all the members of the R group, it is unclear how the limitation applies to alkenyl or alkynyl groups as these groups can only contain two carbons, i.e. two carbons connected by a double bond or two carbons connected by a triple bond.

The recitation "wherein R^L is selected from the group consisting of: a substituted or unsubstituted, linear or branched, saturated or unsaturated C3 to C55 alkyl, heteroalkyl, arylalkyl, alkylaryl chain" renders the claims herein indefinite. It is unclear whether the limitations "substituted or unsubstituted, linear or branched, saturated or unsaturated C3 to C55" refers only to the alkyl chain or whether it is also applied to heteroalkyl, arylalkyl, and alkylaryl chains. Additionally, if it is also applied to heteroalkyl, arylalkyl, and alkylaryl chains, it is unclear whether "C3 to C55" refers only to the alkyl portion or to the entire R^L group.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 8, 14, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a method of inhibiting bacteria by contacting a bacteria with a disaccharide compound of the formula (I).

The MPEP states that for a generic claim, the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. See MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618. Additionally, in *Carnegie Mellon University v. Hoffman-La Roche Inc.*, Nos. 07-1266, -1267 (Fed. Cir. Sept. 8, 2008), the Federal Circuit affirmed that a claim to a genus described in functional terms was not supported by the specification's disclosure of species that were not representative of the entire genus. Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the

genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284/985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The claims are rejected under the written description requirement for failing to disclose a representative number of species for the claimed genus.

The Guidelines for Examination of Patent Applications under the 35 USC § 112, first paragraph, "Written Description" Requirement", published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For claims 1, 3-6, 8, 14, 22 and 24,

each of these factors has been considered, with the most relevant factors discussed below. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high, adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claim 1 and dependent therefrom are directed to a method of inhibiting bacterial growth by contacting a bacteria with at least one disaccharide of general formula (I). Dependent claims 3-6, 8, 14, 22 and 24 further limit the genus of the claimed compounds and genus of bacteria.

Second, how does the scope of the claims compare to the scope of the disclosure? The variables present on the compounds of general formula (I) and the disclosed bacterial strains tested for inhibition of bacterial growth are claimed broader than what is supported in the disclosure. The claims are drawn to a genus of compounds of the formula (I) and a method of inhibiting any bacterial growth, but the disclosure only provides a limited subset of species for the compounds of formula (I), and a limited subset of species of bacterial strains.

Third, the factors need to be considered, with the most relevant factors discussed below.

Reduction to Practice: The compounds reduced to practice are disclosed in Examples 1-6. These disaccharides only comprise galactose and glucose residues. No other sugar residues are disclosed, such as mannose, talose, etc. Additionally, the compounds disclosed in Examples 1-6 only include compounds wherein T is R and R is H; R¹ is CH₂XR and X is O and R is H; and R², R³ and R⁴ is OH. Furthermore, U, W and Z of the disclosed compounds only include N substituted linkages. The bacterial strains reduced to practice include *Micrococcus luteus*, *Staphylococcus aureus*, *Staphylococcus aureus* MRSA, *Enterococcus faecalis*, *Enterococcus faecalis* vancomycin resistant, and *Streptococcus pyogenes*.

Disclosure of Drawings or Structural Chemical Formulas: The only disclosure, in addition to the species reduced to practice, is in the form of lists of possible optional substituents for T, U, W, Z, R¹, R², R³ and R⁴. This type of disclosure is not viewed to be a representation of any of the species it encompasses. A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93 F. 3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there is no disclosure of species (e.g. by disclosure of structural/chemical formulae) in addition to those reduced to practice.

Method of Making the Claimed Invention: The disclosure does not provide a method for the synthesis of any of the compounds of formula (I). The disclosure does provides a method for testing the inhibitory concentration of the disaccharides.

Level of Skill in the Art and Knowledge in the Art: The level of skill in the art for a method of inhibiting bacterial growth is low.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species for the compounds of General Formula (I) or a representative number of bacterial species. Thus, one skilled in the art would lead to conclude that Applicant was not in possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over journal publication by Oki *et al.* (of record) in view of U.S. Patent No. 5,414,073 to Okuyama *et al.* (PTO-892, Ref. A).

Oki *et al.* teach that pradimicin A is an antifungal antibiotic that exhibits antibacterial activity against *Micrococcus luteus* with a MIC value of 3.1 µg/mL (p. 768, subheading "Discussion", paragraph 1).

Pradimicin A differs from the compound of instant claim 1 wherein W is NHR^LR. R^L taught by Oki *et al.* is a methyl group whereas the instant claim specifies that R^L must contain at least 3 carbons.

It would be *prima facie* obvious for one of ordinary skill in the art to substitute the methyl group, with an alkyl group that extends the chain by an additional two carbons. One would have been motivated to make such a substitution with the expectation that the substitution results in a compound that has significant structural similarity to pradimicin A, and would thus possess similar antibacterial properties. See below for recitation of section from MPEP § 2144.09 regarding structural homologs.

The following is a quotation of MPEP § 2144.09:

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Furthermore, such compounds varying only in the chain length of R^L is taught in the Okuyama '073 patent. The Okuyama '073 patent teaches that Y, which is equivalent to variable W of the instant claim, can be NR²R³, wherein one option for R³ is a C1-5 alkyl group.

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Oki *et al.*, concerning the antibacterial activity of pradimicin A, with the teachings of the Okuyama '073 patent, regarding different analogs of pradimicin A. Since the compound taught in the Okuyama '073 patent contains 1-5 carbons at the same position where Oki *et al.* teach that the compound has only one carbon, one would have been motivated to combine the teachings and use a compound wherein the alkyl chain differs only by two homologous units because of the expectation that the substitution results in a compound that has

significant structural similarity to pradimicin A, and would thus possess similar antibacterial properties

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

The following rejections of record from the previous Office Action are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 8, 14, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting bacterial growth by contacting some specific bacteria with a particular disaccharide compound of general formula (I), does not reasonably provide enablement for a similar method of inhibiting bacterial growth by contacting any bacteria with any disaccharide represented by formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure

would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The rejected invention is drawn to a method of inhibiting bacterial growth by contacting any bacteria with any disaccharide represented by formula (I).

Relative skill of those in the art: The relative skill of those in the art is low.

Breadth of claims: The claims are extremely broad in that they encompass all bacteria and all disaccharides of general formula (I).

State of the prior art/Predictability or unpredictability of the art: The skilled artisan would view that it is highly unlikely that one could inhibit any kind of bacterial growth by contacting any bacteria with any disaccharide of general formula (I).

According to the Merck Manual (PTO-892, Ref. U), antibiotics are effective only against certain bacteria. Since antibiotics are drugs designed from antibacterials, the same concept would thus apply. For example, according to the Merck Manual, aminoglycosides are only effective against Gram-negative bacteria such as *E. coli* and *Klebsiella*, macrolides are only effective against streptococcal infections, syphilis,

respiratory infections, myoplasmal infections and Lyme disease, and Linezolid are only effective against Gram-positive bacteria.

Amount of guidance/Existence of working examples: More importantly, working examples are present which only show compounds of general formula (I) wherein T is R and R is H. There are no examples present wherein T is –XR and X is an oxygen, sulphur, or NHC(O)- group. Also, working examples are present to show that only six bacterial strains were tested for inhibition by some disaccharides of general formula (I). Additionally, some disaccharides were tested against some of the six bacterial strains, but not others. For example, as shown in Example 6, compounds 57, 58 and 61 (encompassed in claims 1, 3-6 and 8) were only tested against *S. aureus* (p. 10). Furthermore, working examples specifically show that not all of the disaccharides tested were effective against all of the bacterial strains tested. For example, compound 65 (R1 and R2 is A5 and R3 is A34) was ineffective against *S. aureus*, but effective against *M. luteus* (p. 12).

Lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the use of the claimed compounds in a method of inhibiting bacterial growth, as recited in the instant claims.

Genetech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, e.g., the amount of guidance provided, the predictability of the art and the lack of working examples, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Response to Arguments

Applicant's arguments filed 21 January 2009 with respect to the rejection of claims 1, 3-6, 8, 14, 22 and 24 made under 35 USC § 112, first paragraph, for scope of enablement, have been fully considered but they are not persuasive.

Applicants argue that the disclosure regarding the specificity of the antibiotics in the Merck Manual is insufficient to show non-enablement for the compounds of formula (I). This argument is not persuasive because the Merck Manual specifically indicates that antibiotics are effective only against certain bacteria. Thus, there is currently no known antibiotic that is effective against all types and strains of bacteria. Each type of antibiotic affects a specific mechanism or process of the bacteria. Additionally, it is well-known that resistant bacterial strains are becoming more prevalent, rendering standard antibiotics ineffective. With regards to Applicant's compounds, it is unknown how these compounds exert their antibacterial effect, thereby providing further speculation that each is effective against all types of bacteria. However, even if the mechanism of action

is known, with the emergence of new resistant strains, it is unlikely that the instantly claimed compounds would be effective against all bacterial strains.

The Applicants further argue that the indication of "+" or "-" for the MIC in the tables disclosed in the Specification does not indicate that the compounds, for example, compound 65, is ineffective. Rather, "+" or "-" merely refers to whether the MIC value is above or below 128 µg/mL. This argument is not persuasive because "ineffective" does not indicate that the compound has no activity, but, as Applicant indicated, that it "requires a higher concentration...to achieve stasis in bacterial growth". Therefore, Applicants have themselves set the threshold for determining effectiveness at 128 µg/mL, suggesting that a MIC below this value would not be useful in a method for inhibiting antibacterial growth. Furthermore, as indicated in the rejection above, some of the compounds were only tested against a few bacterial strains, clearly not indicative of the broad spectrum of available known bacterial strains. Additionally, the tested compounds are not representative of the vast array of compounds as instantly claimed since the instant claims encompass compounds of various functional groups, which would conceivably affect its inhibition of bacterial growth.

The rejection is still deemed proper and therefore adhered to.

Conclusion

No claim is allowed. This rejection is made NON-FINAL due to the new/modified grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623